

# Chamber Study Medical Care Overview: Medical Officer's Report

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## SUMMARY

Primary medical and health responsibilities for the Lunar-Mars Life Support Test Project (LMLSTP) were assigned to the Medical Operations Branch at Johnson Space Center (JSC). The prime medical officer for Phases I, II, and IIa, John F. Zieglschmid, M.D., and the prime medical officer for Phase III, Kathleen A. McMonigal, M.D., were designated to carry out these responsibilities, which included medical evaluation and health care of the test subjects. The medical officer was responsible for all medical aspects including pre- and posttest crew medical examinations, ensurance of in-chamber water, and atmospheric gas and food quality. The medical officer also coordinated with principal investigators, demonstration project investigators, the management of the crew and thermal systems division, and the management of the life sciences division. Terrence J. Pattinson, M.D. served in the capacity of Institutional Review Board medical monitor and was deputy medical officer for Phases IIa and III.

### *Pretest Activities*

This medical officer's (KAM) participation in LMLSTP activities began with assignment to the project approximately six weeks prior to the test. This period was occupied with introductions to the investigators and members of the management team, review of the organization of the various supporting functions, crew testing, and examination of prime and back-up test subject crews.

During the pretest period, the medical status of subjects was reviewed in preparation for their entry into the chamber.

### *Phase IIa Test Activities*

#### *Crew Health*

Test subjects complained of eye and mucous membrane irritation shortly after the test began. Investigation revealed significantly elevated formaldehyde levels (up to 0.21 mg/m<sup>3</sup> [ppm]). Newly installed insulation/sound-proofing material was suspected to be offgassing; therefore the material was removed. The formaldehyde levels gradually declined.

One test subject developed biochemical evidence of hypothyroidism two months following test completion. The subject was evaluated and followed prospectively until the thyroid function tests returned to baseline five months later. The test subject appeared to be clinically normal. Consultation with a thyroidologist was conducted. It was concluded that the thyroid changes were likely due to ingestion of excess iodine.

### ***Phase III Test Activities***

A change in the composition of the prime crew was made before the Phase III chamber test when a prime crew test subject developed a disqualifying medical condition prior to start of the test. One of the back-up test subjects moved into the prime crew position.

### ***Crew Health***

One test subject fell on the stairs, sustaining a leg laceration. The injury was examined by the crew medical officer. Under audio and video guidance from the medical officer, the chamber crew provided treatment for the wound. The wound healed satisfactorily without complications.

One test subject sustained an overuse injury of the knee associated with the cycle ergometer. The test subject refrained from lower-extremity exercise for a period of three weeks, until the condition had resolved.

One month after the test began, one test subject was noted to have decreased hemoglobin and red blood cell counts. This anomaly persisted for the remainder of the test, but resolved one month after conclusion of the test. Two other test subjects were also noted to have slightly decreased hemoglobin and red blood cell counts at the conclusion of the test, with resolution of the laboratory abnormalities occurring in these individuals one month after conclusion of the test. After consultation with a hematologist, it was concluded that the hematology changes were likely due to adaptive changes of exercise in two test subjects and to iron deficiency anemia in one test subject (see Chapter 5.1).

### ***Water Quality***

The crew began by drinking iodinated water, 5 mg/L, as was customary for ground-based and space flight crews. Because one test subject from the Phase IIa test had developed subclinical hypothyroidism following test completion, the thyroid function tests of this crew were monitored closely. When the thyroid function tests were evaluated 30 days after the chamber test began, the thyroid-stimulating hormone (TSH) level was 2 to 4 times higher than baseline and the thyroxine

levels had fallen slightly. The 24-hour urine iodine samples showed excretion of 7 to 16 mg iodine. On the 35th day of the test, the iodine was removed from the drinking water following installation of an anion-exchange resin. A 0.2-micron filter was installed at the use port distal to the deiodinator. Subsequently, water samples showed < 0.05 mg/L iodine from the galley sink. Forty-eight hour microbial counts from the deiodinated galley use port were 3 cfu/100 ml or less (with most counts < 1 cfu/100 ml). Thyroid function tests and urine iodine levels were monitored for the remainder of the test. The thyroid function tests returned close to the baseline levels by the completion of the test. Urine iodine levels persisted at ~1 mg/L through the end of the test, although urine iodine samples three days after completion of the test showed values of 0.2 to 0.3 mg/24 hours, which is within the normal range. The cause for the persistently elevated urine iodine levels in the chamber for the last six weeks of the test, at levels greater than that which was expected from the food alone, is uncertain.

#### *Air Quality*

Formaldehyde levels slightly above spacecraft maximum air concentration (SMAC) levels (0.06 to 0.07 mg/m<sup>3</sup>) were identified early in the test and during the last month. No signs or symptoms of skin or mucosal irritation due to the formaldehyde were identified in the crew. The crew was exposed to low levels of diethylamine (~1.58 mg/m<sup>3</sup>) leaking from one component of the air revitalization system, but no symptoms of mucosal irritation were reported.

#### *Posttest Activities*

Three of four test subjects had a 6- to 9-pound weight loss during the Phase III test. The hematology values in the Phase III test subjects returned to baseline levels after cessation of the exercise protocol.

The thyroid function tests in the Phase IIa test subject, as mentioned previously, returned to baseline seven months after study completion. One test subject in the Phase III test developed biochemical evidence of hyperthyroidism five months after study completion (seven months after discontinuing iodinated water consumption). Consultation with a thyroidologist was obtained. It was concluded that the thyroid test changes were likely due to excess iodine ingestion even though the iodine had been discontinued some months earlier. Thyroid function tests returned to baseline 10 months after study completion (12 months after discontinuing iodinated water consumption). The test subject appeared to be clinically normal. There were no other significant changes in the crew health, which could be attributed to the chamber stay.

### ***Recommendations for Future Chamber Studies***

Medical monitoring of the test subjects was hampered by inadequate documentation of medical history and physical examination and a lack of essential laboratory tests and ancillary studies obtained prior to the start of the project. Therefore, after completion of the LMLSTP study, test subject medical selection requirements were written and approved by the Aerospace Medicine Board (see Appendix). These include appropriate medical history, physical examination, laboratory, and ancillary testing, with comprehensive documentation essential to the medical evaluation of an individual's health status.

Two injuries occurred over the course of the project. A laceration from contact with the ladder was effectively managed by the in-chamber crew acting under direction of the physician medical officer using telemedicine audio/video. In selected cases of minor illness or injury, appropriately trained chamber crew can provide limited medical care under the direction of the medical officer who has conducted telemedicine evaluation of the test subject. Such treatment must be carefully monitored by the physician medical officer. Medical supplies for the chamber should be expanded from the current minimal configuration to include appropriate supplies, medication, and equipment that could be used in these cases.

The second injury, an overuse injury during an exercise protocol, resolved after the test subject refrained from lower-extremity exercise for a period of three weeks. Increases in workload during exercise protocols should be carried out with appropriate consultation and communication between the subject, the principal investigator, and the medical officer. This may help to decrease the probability of the occurrence of training injuries resulting from increases in workload.

Three test subjects exhibited decreased hemoglobin levels. Two of these cases were found to be due to increased plasma volume as the result of exercise, while the third case was determined to be due to iron deficiency. Although exercise-induced "anemia" is likely to occur in this setting, the medical officer must rule out other possible causes of anemia including occult bleeding, hemolysis, marrow failure, anemia associated with illness, nutritional deficiency, or other causes.

Iodine will continue to be used for the disinfection of the water. Although iodine will be removed from the drinking water, iodinated water will still be present in the shower water and wash water. Ongoing monitoring of the water recycling system will be necessary to ensure proper functioning of the filters and resins and maintenance of microbial control.

The Phase IIa crew experienced skin and mucous membrane irritation from formaldehyde offgassing from newly installed insulation/sound-proofing material. Formaldehyde was specifically monitored from various locations during the

Phase III test by analysis of badge samples to ensure levels remained within the acceptable range. Particular attention to crew symptoms must continue when new or untested materials are introduced into a sealed environment.

### ***Appendix***

Subject: Policies and Procedures for Selection Medical Examinations and Medical Certification of Closed Chamber Study Test Subjects

Responsible Individual(s): physicians conducting selection medical examinations and medical certification of closed chamber studies test subjects.

#### **1. PURPOSE**

The purpose of this document is to provide standard policies and procedures for selection medical examinations and medical certification of closed chamber studies test subjects.

#### **2. SCOPE**

These policies and procedures apply to physicians who conduct medical evaluations to determine the medical qualification of individuals undergoing selection for positions as human test subjects in closed chamber studies in which Institutional Review Board (IRB) review and approval is required.

#### **3. REFERENCES**

- a. Air Force Instruction 48-123, "Medical Examination and Standards."
- b. NASA Management Instruction (NMI) 7100.8, "Protection of Human Research Subjects."
- c. NASA IOHERD, "Human Experimental and Research Data Records," Privacy Act of 1974, Systems of Records.
- d. NASA 10 HIMS, "Health Information Management," Systems of Records.
- e. JSC Management Instruction (JMI) 1382.8, Privacy Act of 1974.11
- f. JSC-20483, "Revision B II JSC Institutional Review Board – Guidelines for Investigators Proposing Human Research for Space Flight and Related Investigations."

#### **4. PROCEDURE**

Medical evaluation of individuals for the purpose of medical selection and medical certification for participation in closed chamber studies human research tests shall be conducted in accord with the above referenced policy directives. In addition to the published directives, the following procedures will apply.

- a. Medical examinations and evaluations will be conducted by physicians who are familiar with the medical issues of long duration, closed chamber tests.
- b. The minimum medical standards for selection of closed chamber studies test subjects will be those standards that are required to be met for Air Force Class III medical certification. The document defining those standards is Air Force Instruction 48-123, "Medical Examination and Standards."
- c. Additional requirements for certification may include mission or test specific medical requirements as established by the responsible test physician.
- d. Completion of SF form 93 and the NASA Medical Survey (JSC form 1639) is to be done by the subject prior to the physical examination. The physician will review these forms, interview the subject with attention to positive disclosures on the forms and make appropriate comment on the medical record.
- e. A comprehensive history and physical examination shall be conducted for each subject and will be documented in typewritten or computer-printed standard narrative format including:
  - 1) purpose of the examination
  - 2) history of any present illness
  - 3) past medical history including an appropriate discussion of illnesses, surgery, injuries, transfusions and allergies
  - 4) family medical history
  - 5) social history
  - 6) health habits including alcohol, drug and cigarette use
  - 7) occupational history including exposure to toxins, radiation or pathogens.
- 8) Physical examination of all systems will be comprehensive in nature, however a female subject may provide medical records of pelvic examination and Pap smear within the preceding year by her private physician, as an alternative to examination by the NASA physician.
- f. Appropriate documentation of the history and physical examination will include the specific negative as well as the specific positive findings for each system that is examined. The history and physical examination will be documented in standard narrative format that will be computer-printed or typewritten. In addition to the narrative, an SF form 88 will be completed by the physician.
- g. The minimum laboratory tests that will be obtained will include the following:

- 1) CBC with differential count and reticulocyte count
- 2) urinalysis
- 3) chemistry panel
- 4) lipid profile
- 5) thyroid panel, free T4, thyroid autoantibodies
- 6) serum iron, iron binding capacity, percent iron saturation, ferritin
- 7) hepatitis A Ab, hepatitis BsAg, hepatitis C Ab
- 8) HIV antibody
- 9) stool hemocult if 40 years of age or older
- 10) urine pregnancy test, if female
- h. Other tests/examinations will include:
  - 1) height, weight and vital signs
  - 2) visual acuity and intraocular pressure
  - 3) audiometry
  - 4) tuberculin skin test, unless previously positive or if the individual has received BCG in the past
  - 5) chest x-ray within 5 years
  - 6) pulmonary function test
  - 7) treadmill exercise ECG (Bruce or Cunningham)
- i. For medical screening purposes, a psychiatric evaluation will be conducted by a psychiatrist and a psychologist with expertise in the area of crew selection for unusual or extreme environments. This evaluation will be comparable to the 'select-out' evaluation administered to astronaut applicants and will consist of psychological testing and a structured clinical interview. Selection criteria will be the same as the selection criteria and procedures currently in use for astronaut selection. However, modifications will be made depending upon the length of the mission:
  - 1) *Missions < 30 days.* A subset of the current psychological battery will be given; specifically, the Family History Questionnaire, MMPI-2 and NEO-PI-R will be used. A full version of the current structured clinical interview will be administered.
  - 2) *Missions 30 or more days.* All tests which are a part of the current psychological battery will be included. At present, these are FHQ, MMPI-2, NEO-PI-R, and FSSCT. A full version of the current structured clinical interview will be administered and any further diagnostic tests applicable to astronaut selection at that time.
  - 3) The medical screening process will share psychological test and interview data, as well as interview time, with the suitability ('select-in') process.

Psychiatric certification of the test subject by the examining psychologist and psychiatrist as "qualified for closed chamber test crew" will be required for subject participation as a crewmember.

- 4) A separate, non-medical 'select-in' evaluation will also be conducted on each applicant by a psychologist with expertise in assessing psychological suitability of candidates for extreme or confined environments.  
However, the results of this evaluation do not affect determination of a subject's Class III medical certification, and recommendations derived from this 'select-in' examination are forwarded to the closed chamber test selection committee for consideration in their crew selection decisions.
- j. Dental examination must be conducted within one year prior to the selection physical examination. The subject shall provide certification of dental health documenting the absence of current dental pathology. All required dental care should be completed by the time of selection examination or soon thereafter.
- k. Medical consultation will be obtained at the discretion of the examining physician.
- l. Additional laboratory or ancillary tests may be ordered at the discretion of the examining or consulting physicians.
- m. The examining physician will determine whether the subject meets the requirements for Air Force Class III medical certification.
- n. The Aerospace Medical Board may consider waiver for conditions that are disqualifying for Air Force Class III medical certification, if in the opinion of the Board, such disqualifying condition would not constitute a threat to the health and safety of the subject or other persons, or to the successful completion of the test.
- o. Any medical condition or defect that develops in a test subject who is certified must be reported to the test physician. Any condition that in the opinion of the physician presents a hazard to the individual's health or to mission completion is cause for withholding certification for initial participation or disqualification for continued participation. To be considered waiverable, any disqualifying condition should meet the criteria as outlined in the above directives.

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